

REMARKS

In the communication dated May 16, 2003, the Examiner states that Applicants election filed February 24, 2003 was non-responsive. Reconsideration is respectfully requested.

Claims 52 – 58 have been amended to include the SEQ ID NO: of the peptide component of the depicted chemical structure, as required by the Examiner. Claims 1-58 are pending.

Restriction Requirement

The Examiner asserts that the communication filed February 24, 2003 is non-responsive because the claims have been amended to include multiple independent claims within the same claim.

In paragraph 2, the Examiner states that the claims were amended to include multiple distinct inventions within the same claim. Specifically, the Examiner states that there appear to be three different products in the claimed invention: (i) natural viral variants of HIV-1 gp41 DP-178 (aa638-673); (ii) amino-terminal truncations of DP-178; and (iii) variants of DP-178 containing single amino acid substitutions. The Examiner requires Applicants to select a single group of peptides (one of the peptide groups set forth in (i), (ii), or (iii)). The Examiner further concludes that he would consider a single method of using the elected peptides as set forth in claims 44-47.

In paragraph 3, the Examiner further states that the application includes a number of other groups which do not share a special technical feature with the aforementioned groups. Specifically, the Examiner states that claims 32-35, 40-43, and 48-51 directed to various DP-178 peptides that have been conjugated to a blood component, and to a method of use. The Examiner states that these peptides share a different chemical structure (conjugated v. unconjugated) which will impart different functional activities upon each group of peptides.

Applicant's Response

Applicants elect group (i) directed to natural viral variants of HIV gp41 DP178, with traverse.

Applicants respectfully request that the Examiner reconsider his position with regard to group (ii), directed to three amino-terminal truncations. The Examiner argues that the truncated

peptides all show reduced anti-viral activity. Specifically, the Examiner argues that Table 2 of Lawless et al. (submitted by Applicants in the Information Disclosure Statement of February 20, 2003) shows that the truncated peptides all show a decrease in T21 binding activity. Contrary to the Examiner's assertion, however, Lawless interprets Table 2 to show that "identical results are shown for the first two truncated peptides, ...indicating that the three N-terminal residues are not essential in producing this structural interaction" (Lawless et al., page 13704, column 1).

Lawless et al. further states that "the removal of 1 or 3 N-terminal residues from T20 has no effect on the peptide's ability to interact with T21 or inhibit membrane fusion" (Lawless et al., page 13709, column 1, section entitled "Correlation of Structural Interactions with Antiviral Results," Emphasis added). These explicit statements of Lawless et al. directly contradict the Examiner's assertion that the substitutions would affect the peptide's activity in an unpredictable manner. The Examiner is respectfully requested to reconsider his position and examine these truncations in this case.

Applicants also respectfully request that the Examiner reconsider his position with regard to group (iii), directed to variants containing single amino acid substitutions. The Examiner alleges that Lawless et al., Table 2 "illustrates that single amino acid substitutions also affect the peptide activity in an unpredictable manner." The single amino acid substitutions claimed herein, however, are trivial substitutions known to have no effect, or a negligible effect, on the activity of the peptide. The naturally occurring DP-178 peptides, along with the single amino acid substitutions, are together single inventive concept. The Examiner is respectfully requested to reconsider his position and examine these single amino acid substitutions and analogs in this case.

Conjugated and Unconjugated Modified Peptides

The Examiner states in paragraph 3 of the communication dated May 16, 2003 that the application includes a number of other groups that in this case do not share a special technical feature with the aforementioned groups.

In contrast to the Examiner's assertion, claims 32-35 and 40-43 share a special technical feature with the modified peptides of claim 1 and those depending therefrom. Claims 1-6, 19-21, and 31 are directed to a modified peptide that reacts with blood components. The modified peptides of claims 1-6, 19-21, and 31 are merely intermediate reacting compounds of the final

peptide covalently bonded to a blood component of claims 32-35. Similarly, claims 40-43 are directed to compositions including the same final conjugated product of claims 32-35. Claims 48-51 are methods of using the modified antiviral peptide of claim 1 to treat human immunodeficiency virus (HIV) infection in a patient by forming a covalent bond between the modified anti-viral peptide of claim 1 and the blood component.

Since the modified peptides of claims 1-6, 19-21, and 31 are intermediate reacting compounds of the final covalently bonded compounds of claims 32-35 and 40-43, which may be made by the methods of claims 48-51, the Examiner is respectfully requested to reconsider his position and examine the conjugated and unconjugated modified peptides.

Claims 52-58 Sequence Identifiers

In paragraph 2, the Examiner states that claims 52-58 “fail to provide appropriate sequence identifiers.” The claims are drawn to covalently modified SEQ ID NO:1. Applicants have added the limitation “SEQ ID NO:1-Lys-(ϵ -MPA)” to claims 52-58 to more clearly identify the peptide sequence component of each chemical structure.

This amendment only makes explicit what was already implicit in the claims.

Conclusion

Applicants respectfully submit that the claims are now in condition for allowance.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this

document to **Deposit Account No. 03-1952** referencing docket no. **500862001520**. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

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By:

Michael R. Ward
Michael R. Ward
Registration No. 38,651

Morrison & Foerster LLP
425 Market Street
San Francisco, California 94105-2482
Telephone: (415) 268-6237
Facsimile: (415) 268-7522